REMARKS

Claims 26 and 38-39 are currently pending in the present application. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Priority

The Official Action states that applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:

> Applicant claims ultimate priority to Provisional Application Serial No. 60/001,796, filed August 2, 1995. This priority claim cannot be granted because the line of cases stemming from the '796 provisional applicant lacks copendency with the case under examination. Specifically, applicant asserts that this application is a continuation in part of 09/770,253, which is in turn a continuation in part of the '796 provisional application. Continuations in part of provisional applications do not exist. Rather, one can obtain priority to a provisional application only by filing a non-provisional application within 12 months of filing the provisional application. See 35 U.S.C. 119(e). The '253 application was filed on January 29, 2001, more than 12 months after the August 2, 1995, filing date of the '796 provisional application. Applicant's claim of priority from the '253 application to the '796 provisional application clearly cannot be granted.
>
> It is noted that Application Serial No. 08/700,760 was filed on July 29, 1996, less than 12 months after the August 2, 1995, filing date of the '796 provisional application. However, the '760 application ultimately issued as U.S. Pat. No. 6,118,045, on September 12, 2000. Because the '253 application was not filed until January 29, 2001, the '253 application was not copending with the

> '760 application. The '253 application therefore cannot be granted priority based on the '760 application. Applicant also claims priority through the '253 application to Provisional Application Serial No. 60/111,291, filed December 7, 1998, which was a priority document to PCT/US99/29042. This priority claim cannot be granted for two reasons. First, as discussed above, a priority claim to a provisional application must be made within twelve months of the filing of the provisional application. See 35 U.S.C. § 119(e). The '253 application was filed January 29, 2001, more than 12 months after the December 7, 1998, filing of the '291 provisional. Second, the '253 application contains no inventors in common with either the '291 provisional application or the '042 PCT application. Thus, even if the PCT application is considered to be copending with this application or the '253 application, priority cannot be granted because there are no inventors in common between this case and the '253 application, and the '291 provisional application and the '042 PCT application. In sum, the earliest priority date applicant can be granted is January 29, 2001, the filing date of Application Serial No. 09/770,253, the C-I-P parent of this case.

Applicants thank the Examiner for pointing out the deficiency in the present claim to priority. A mistake was made in the recitation of the claim to priority at the time the present application was filed. Accordingly, applicants submit with this response a Request for Corrected Official Filing Receipt (applicant mistake) to amend and correct the claim to priority. Once this change is made, the present application will properly claim priority to Provisional Application Serial No. 60/001,796, filed August 2, 1995.

In particular, the correct claim to priority includes a claim as a CIP of U.S. Patent Application Serial No. 09/770,253, filed

January 29, 2001 and as a CIP of U.S. Patent Application Serial No. 10/046,180, filed January 16, 2002, which is a Reissue of U.S. Patent No. 6,118,045, filed as 08/700,760 on July 29, 1996. The Examiner has already acknowledged on the record that the '760 application is entitled to the priority date of Provisional Application Serial No. 60/001,796, filed August 2, 1995; accordingly, the present claim for priority to the reissue application resulting from the original '760 application properly is entitled to the '796 application priority date of August 2, 1995. Further, by rejecting the presently pending claims under 35 U.S.C. 102 over the '045 patent, as discussed below, the Examiner has admitted on the record that the '045 patent specification (and accordingly the '180 application specification) is an enabling reference for the presently claimed invention. Accordingly, the revised claim to priority submitted herein is proper.

Accordingly, applicants respectfully request the Examiner to correct the instant claim to priority as per the attached Request so that the present application properly claims priority to August 2, 1995.

2. Rejection of Claim 26 under 35 U.S.C. § 112, 2d paragraph

The Official Action states that claim 26 is rejected under 35 U.S.C. § 112, second paragraph for the following reasons:

> Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicants regards as the invention.
A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 26 recites the broader recitation of purity of 95%, and the claim also recited preferable purities of 99% and 99.9%, which are the narrower statements of the range/limitation.
Claim 26 is also rendered indefinite by the recitations "preferably" and "more preferably". Because a preference is an entirely subjective criterion, and because it is not clear when the preferences must be exercised, the claim must be considered indefinite.
Also, the recitation "a-glucosidase" is technically an incorrect designation for the enzyme. Specifically, the enzyme may be correctly referred to as -- α-glucosidase -- or -- alpha-glucosidase --.

Applicants respectfully traverse this rejection. Regarding the §112, second paragraph rejection, caselaw has defined two requirements under the statute: (1) whether the applicant has stated the invention as something elsewhere in the application which would not fall under the scope of the claims; and (2) whether the claims would be communicated with a reasonable degree of particularity and distinctness to a person skilled in the art in light of the content of the disclosure and the teachings of the

prior art. MPEP §2171, §2173, and §2173.02.

Applicants thank the Examiner for his suggestions regarding the claims. Accordingly, applicants have amended claim 26 to remove the "preferred ranges" and to recite "α-glucosidase" rather than "a-glucosidase". Additionally, applicants have added new claims 38-39 directed to the preferred ranges removed from claim 26.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 26.

3. Rejection of Claim 26 under 35 U.S.C. § 102(b)

The Official Action states that claim 26 is rejected under 35 U.S.C. § 102(b) as being anticipated by Van Corven et al. (WO 99/51724).

As the basis of this rejection, the Official Action states:

> Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Van Corven et al (WO 99/51724).
> Van Corven describes the intravenous administration of up to 10 mg purified human acid α-glucosidase to patients suffering from lysosomal enzyme deficiency disease. See, e.g., page 32, lines 4-19. Note specifically that the reference inherently meets the claimed limitation requiring liver, heart and muscle cell uptake because the reference describes administering the same ingredient to the same patient at the same dosage. Note further that the reference also discloses the claimed purity limitation, stating on page 21, lines 13-17 that the most preferred pharmaceutical compositions comprise essentially homogenous enzyme. A holding of anticipation is clearly required.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is

found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants note that the Van Corven reference cited by the Examiner was published on October 14, 1999. In contrast, as discussed in Section 1 above, the arguments of which are herein incorporated by reference in their entirety, the present application properly claims priority to August 2, 1995. Since the priority date for the present application is before the publication date of the cited Van Corven PCT publication, Van Corven et al. is not actually prior art against the present application, rendering the present rejection moot.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 26.

4. Rejection of Claim 26 under 35 U.S.C. § 102(b)

The Official Action states that claim 26 is rejected under 35 U.S.C. § 102(a) as being anticipated by Van Bree et al. (WO 00/34451).

As the basis of this rejection, the Official Action states:

> Claim 26 is rejected under 35 U.S.C. 102(a) as being anticipated by Van Bree et al (WO 00/34451).
> Van Bree describes the intravenous administration of up to 40 mg purified human acid α-glucosidase to patients suffering from Pompe's disease, and that the enzyme will be taken up by liver, heart and muscle cells. See, e.g., page18, line 7, through page 19, line 20. Note further that the reference also discloses the claimed purity limitation, stating on page 5, lines 22-25, that the most preferred pharmaceutical compositions comprise essentially homogenous enzyme. See also page 17, lines 23-28, disclosing greater than 95% pure enzyme from transgenic rabbits. A holding of anticipation is clearly required.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants note that the Van Bree reference cited by the Examiner was published on June 15, 2000. In contrast, as discussed in Section 1 above, the arguments of which are herein incorporated by reference in their entirety, the present application properly claims priority to August 2, 1995. Since the priority date for the present application is before the publication date of the cited Van Bree PCT publication, Van Bree et al. is not actually prior art

against the present application, rendering the present rejection moot.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 26.

5. Rejection of Claim 26 under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e)(2) and 35 U.S.C. § 102(f)

The Official Action states that claim 26 is rejected under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e)(2) and 35 U.S.C. § 102(f) as being anticipated by Reuser et al. (US 6,118,045).

As the basis of this rejection, the Official Action states:

> Claim 26 is rejected under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e)(2) and 35 U.S.C. § 102(f) as being anticipated by Reuser et al (U.S. Pat. 6,118,045). Reuser discloses the administration of human acid α-glucosidase to a patient suffering from Pompe's disease, wherein the enzyme is purified to homogeneity. Note specifically that the reference inherently meets the claimed limitation requiring liver, heart and muscle cell uptake because the reference describes administering the same ingredient to the same patient at the same dosage. See claims 18-20, at column 18, lines 38-47. Note further that therapeutic dosages are defined therein as generally from about 0.1 to 10 mg purified enzyme per kilogram of body weight. See column 12 at lines 20-23. A holding of anticipation is clearly required.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in

the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants note that, as discussed in Section 1 above, the arguments of which are herein incorporated by reference in their entirety, the present application properly claims priority to August 2, 1995 by virtue of, among others, U.S. Patent No. 6,118,045. Since the present application claims priority to the cited Reuser patent, the Reuser patent cannot actually be considered prior art against the present application, rendering the present rejection moot.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 26.

6. Rejection of Claim 26 for Obviousness-Type Double Patenting

The Official Action states that claim 26 has been rejected for the following reasons:

> Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20 of U.S. Patent No. 6,118,045. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although they recite a product, the patented claims use terminology clearly suggesting the treatment of Pompe's disease by intravenous administration of homogenous enzyme. Moreover, by properly construing the term "therapeutically effective dosage" by reference to the specification (column 12, lines 20-20), it is clear that such dosages fall within those present in the claims under examination. Further

> still, the determination of suitable dosages was well within the purview of the artisan of ordinary skill at the time of applicant's invention. Claim 26 is clearly not patentably distinct from claims 18-20 of the '045 patent.

Applicants thank the Examiner for his suggestions regarding the claims. Accordingly, applicants have filed herewith a terminal disclaimer against U.S. Patent No. 6,118,045 in accordance with MPEP § 804.02, removing the present grounds for rejection.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection to pending claim 26.

CONCLUSION

Based upon the above amendments and remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of pending claims 26 and 38-39. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,

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